

What is claimed is:

1. A sterilized fluid management kit for use in renal replacement therapy, comprising:

a filter with a membrane, a replacement fluid container, and a filtrate container;

a filtrate circuit connected to said filter, said filtrate circuit having a connector for connection to a source of fluid;

said membrane having a pore size effective to reduce pyrogenic material to a level safe for infusion;

a blood circuit with venous and arterial blood lines and a blood side of said filter and terminated with connectors for connection to a patient access;

said venous blood line having a branch terminated by a connection to said replacement fluid container;

said blood circuit being entirely sealed and pre-sterilized except for fluid communication, through a membrane of said filter, with said filtrate circuit such that raw fluid may be pumped through said membrane into said replacement fluid container with no opportunity for coming into contact with a non-purified surface after passing through said membrane;

whereby sterility of replacement fluid placed in said replacement fluid is assured.

2. The kit of claim 1, wherein said replacement fluid container and said replacement fluid branch are permanently connected to said venous blood line.

3. The kit of claim 2, wherein said filtrate circuit, said filter, said venous blood line, and said replacement fluid container are connected such that a direct fluid path from said filtrate circuit connector to said replacement fluid container is defined.

4. The kit of claim 3, wherein said filtrate circuit includes a pumping portion, whereby fluid may be pumped through said direct fluid path into said replacement fluid container.

5. The kit of claim 4, wherein said filtrate circuit, said filter, said venous blood line, and said replacement fluid container are connected such that a direct fluid path from said filtrate circuit connector to said replacement fluid container is defined.

6. The kit of claim 5, wherein said filtrate circuit includes a pumping portion, whereby fluid may be pumped through said direct fluid path into said replacement fluid container.

7. The kit of claim permitting said to enable fluid to be directed to engageable with a pump actuator for

8. The kit of claim 2, wherein a first one of the plurality of tubes is a blood draw line.

9. The kit of claim 21, wherein a second one of the plurality of tubes is a blood return line.

10. The kit of claim 22, wherein a third one of the plurality of tubes is a replacement fluid line or waste line.

11. The kit of claim 19, further including a connector, and wherein a second end of at least one of the plurality of tubes is releasably connected to the purified replacement fluid reservoir by the connector.

12. The kit of claim 24, wherein the connector is adapted to releasably couple to a vascular access device.

13. The kit of claim 24, wherein the connector is a Luer connector.

14. The kit of claim 19, further including a sterilized cap, and wherein the sterilized cap removably seals the second end of the replacement fluid container tube.

15. A method for performing renal replacement therapy with a treatment device that employs a fluid circuit with liquid and blood fluid circuits separated by a membrane, the membrane having a pore size effective to block the passage of pyrogenic material, the method comprising the steps of:

connecting a source of electrolytically-balanced fluid to the liquid fluid circuit;

ensuring sterility of said electrolytically-balanced fluid by passing the same through said membrane to produce sterile fluid and storing said sterile fluid in a reservoir;

warming and maintaining a temperature of said sterile fluid until a treatment time;

recirculating said sterile fluid through said reservoir during a first phase of priming to permit gas to be purged from said sterile fluid and prime a first portion of said fluid circuit;

priming a further portion of said fluid circuit.

16. A method as in claim 1, wherein said step of priming a further portion is executed after said step of recirculating.

17. A method as in claim 1, further comprising conveying blood from a patient through said blood fluid circuit during a treatment cycle and removing waste from said blood from said blood fluid circuit through said membrane to said liquid fluid circuit.

18. A method as in claim 1, further comprising adding said sterile fluid from reservoir to said patient.

19. A method as in claim 1, wherein said step of ensuring sterility includes ensuring a rate of endotoxins below

a predetermined level by filtering with a membrane with a pore size effective to limit endotoxins.

20. A method as in claim 5, wherein said predetermined level is 3 EUs/ml. or less.

21. A method as in claim 2, wherein said step of adding is performed substantially simultaneously with said step of removing.

22. A method as in claim 1, further comprising the step of vibrating said reservoir to aid in the removal of gas.

23. A method as in claim 1, wherein step of pumping said electrolytically-balanced fluid from the source includes operating a blood pump in a first direction and said step of conveying blood includes operating said blood pump in a second direction opposite said first.

24. A method for performing renal replacement therapy with a treatment device that employs a fluid circuit with fluid and blood circuits separated by a membrane, the membrane having a pore size effective to block the passage of pyrogenic material, the method comprising the steps of:

at a predetermined time prior to a treatment time, automatically preparing a batch of replacement fluid by filtering unfiltered replacement fluid with said membrane and

storing filtered replacement fluid, resulting from said step of preparing, in a reservoir;

initiating a step of priming said fluid circuit with said filtered replacement fluid responsively to a signal indicating one of a passage of an interval of time, a mass of filtered replacement fluid, and a mass of unfiltered replacement fluid;

initiating a step of warming said filtered replacement fluid responsively to a predetermined time before said treatment time;

initiating a step of treating responsively to an indication of a completion of said step of priming.

25. A method as in claim 9, wherein said indication of a completion of said step of priming includes a change in a level of air in said fluid circuit.

26. A method as in claim 9, wherein said step of warming includes maintaining a predetermined temperature of said filtered replacement fluid.

27. A method as in claim 9, further comprising measuring a pressure of said filtered or said unfiltered replacement fluid upstream of a filter and generating an alarm when said pressure falls below a predetermined level or changes faster than a predetermined rate.

28. A method as in claim 9, further comprising the step of insulating said filtered replacement fluid.

29. A method as in claim 9, wherein said step of treating includes passing blood through said blood fluid circuit such that filtrate passes through the same membrane to said liquid fluid circuit such that a same membrane is used to generate sterile replacement fluid and treat a patient.

30. A fluid circuit for a blood treatment system, comprising:

a blood filter or dialyzer with a blood circuit and a replacement fluid container with a replacement fluid circuit connected to said blood circuit for diluting blood;

said blood circuit communicating with a blood side of said blood filter or dialyzer having and having at least one patient access port connected to said replacement fluid container to define a recirculation path;

a port on a non-blood side of said filter connectable to a source of replacement fluid;

said recirculating path being entirely hermetically isolated from an outside of said fluid circuit except by a flow path through a membrane of said filter or dialyzer from said non-blood side to said blood side such that replacement fluid may be added to said replacement fluid container through said

filter or dialyzer membrane and stored therein and a flow through said recirculating path may be established without making any connections or disconnections breaking said hermetic seal.

31. A fluid circuit as in claim 16, wherein said replacement fluid circuit is connected to said blood circuit by said replacement fluid circuit, said patient access port is connected to said replacement fluid container by at least one access line, and said recirculating path is defined by at least a portion of each of said blood circuit, said access line, and said replacement fluid replacement fluid circuit.

32. A fluid circuit as in claim 17, wherein said access line includes two tubes making a parallel connection between said blood circuit and said replacement fluid container.

33. A fluid circuit as in claim 16, wherein said replacement fluid circuit includes an inline component including at least one of an inline filter effective to block pyrogens and/or air and a fluid property sensor connectable to a controller or alarm.

34. A fluid circuit as in claim 19, wherein said inline component is located immediately upstream of a junction with said blood circuit.

35. A fluid circuit as in claim 20, wherein said inline component includes filter effective to reduce endotoxins to a rate of less than 3 EUs/ml.

36. A fluid circuit as in claim 16, wherein said recirculating path includes an access needle.

37. A fluid circuit as in claim 22, wherein said access needle forms part of a connector connecting said replacement fluid container via said access line to said blood circuit, said connector having a portion that automatically seals said access line when disconnected to make said access needle available for accessing the blood flow of a patient in preparation for treatment.

38. A fluid circuit as in claim 16, wherein said replacement fluid container has ports forming part of said recirculation path, said ports being arranged to prevent short-circuit flow therebetween, whereby bubbles may settle out of said recirculating flow into said replacement fluid container.

39. A fluid circuit as in claim 24, wherein said replacement fluid container is at least 5 l. in volume.

40. A dialysis fluid circuit, comprising:

a connection for a source of dialysate connectable to a dialysate side of a dialyzer;

a blood circuit connected to a blood side of said
dialyzer;

said blood circuit being connected to a replacement
fluid container to form a circuit leading through said filter to
said replacement filter container while otherwise hermetically
sealing said replacement fluid container from an external
environment whereby dialysate may be sterile filtered by passing
from said dialysate side to said blood side of said dialyzer and
stored in said replacement fluid container for use in treatment
at which time said dialyzer is free for use for dialysis.

41. A fluid circuit as in claim 26, wherein said
blood circuit includes venous and arterial lines, each connected
to said replacement fluid container.

42. A fluid circuit as in claim 26, further
comprising a balancing circuit that receives spent dialysate
from said dialysis side to dispense raw dialysate at a rate that
is substantially the same as said spent dialysate is received
thereby.

43. A fluid circuit as in claim 26, wherein said
blood circuit is connected to said replacement fluid container
by a line having a pumping portion whereby replacement fluid
stored in said replacement fluid container may be dispensed for
treatment.